

What is claimed is:

Patent

1. A pharmaceutical composition which comprises a lipase inhibitor and a pharmaceutically acceptable bile acid sequestrant.
2. The composition according to claim 1 further comprising one or more pharmaceutically acceptable excipients.
3. The composition according to claim 1, wherein the lipase inhibitor is orlistat.
4. The composition according to claim 1, wherein the pharmaceutically acceptable bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, colesevelam, colestipol, sevelamer, cellulose derivatives, dextran derivatives, starch, starch derivatives, and pharmaceutically acceptable salts thereof.
5. The composition according to claim 4, wherein the bile acid sequestrant is a cellulose derivative or dextran derivative.
6. The composition according to claim 5, wherein the cellulose derivative or dextran derivative is selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex.
7. The composition according to claim 4, wherein the starch or starch derivative is selected from the group consisting of β -cyclodextrin, γ -cyclodextrin, retrograded starch, degraded starch, a combination of retrograded and degraded starch, hydrophobic starch, amylose, starch-diethylaminoethylether, and starch-2-hydroxyethylether.
8. The composition according to claim 7, wherein the starch or starch derivative is β -cyclodextrin or γ -cyclodextrin.
9. The composition according to claim 4, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, colesevelam, colestipol, sevelamer,

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cellulose, DEAE-cellulose, guanidinoethylcellulose, DEAE-Sephadex, starch, β -cyclodextrin, and γ -cyclodextrin.

10. The composition according to claim 9, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin.

11. The composition according to claim 10, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin.

12. The composition according to claim 11, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, and sevelamer.

13. The composition according to claim 12, wherein the bile acid sequestrant is cholestyramine.

14. The composition according to claim 12, wherein the bile acid sequestrant is colestipol.

15. The composition according to claim 12, wherein the bile acid sequestrant is sevelamer.

16. The composition according to claim 2, wherein the pharmaceutically acceptable excipient is selected from the group consisting of fillers, surfactants, disintegrants, binders, lubricants, flowability enhancers, sweeteners, and colorants.

17. The composition according to claim 1, wherein the composition comprises (a) from about 5 to about 1000 mg of a lipase inhibitor and (b) from about 0.1 to about 20 g of a bile acid sequestrant.

18. The composition according to claim 17, which comprises:
(a) from about 5 to about 1000 mg of a lipase inhibitor;
(b) from about 0.1 to about 20 g bile acid sequestrant;

(c) from about 0.1 to about 10 g of a filler;
(d) from about 0.05 to about 3.0 g of a surfactant;
(e) from about 0.05 to about 2.0 g of a disintegrant;
(f) from about 0.02 to about 2.0 g of a binder;
(g) from about 0.001 to about 1.0 g of a lubricant;
(h) from about 0.1 to about 5.0 g of a flowability enhancer;
(i) from about 0.01 to about 4.0 g of a sweetener; and
(j) and about 0.001 to about 0.5 g of a colorant.

19. The composition according to claim 17, wherein the lipase inhibitor is orlistat.

20. The compositions according to claim 19, wherein the lipase inhibitor is present in an amount of from about 10 to about 500 mg.

21. The composition according to claim 20, wherein the lipase inhibitor is present in an amount of about 120 mg.

22. The composition according to claim 20, wherein the lipase inhibitor is present in an amount of from about 20 to about 100 mg.

23. The composition according to claim 22, wherein the lipase inhibitor is present in an amount of about 60 mg.

24. The composition according to claim 17, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g.

25. The composition according to claim 25, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g.

26. A kit for use in the treatment of obesity, which comprises (a) a first component which is a lipase inhibitor and (b) a second component which is a bile acid sequestrant, present in oral unit dosage form.

28. A method of treating obesity in an obese patient, which comprises administering to a patient in need of such treatment (a) a therapeutically effective amount of a lipase inhibitor and (b) a pharmaceutically acceptable bile acid sequestrant in an amount effective to reduce gastrointestinal side effects associated with the lipase inhibitor.

29. The method according to claim 28, wherein the lipase inhibitor and bile acid sequestrant are administered simultaneously.

30. The method according to claim 28, wherein the lipase inhibitor and bile acid sequestrant are administered separately.

31. The method according to claim 28, wherein the lipase inhibitor and bile acid sequestrant are administered sequentially.

32. A method of reducing the gastrointestinal side effects associated with the lipase inhibitor treatment, which comprises administering to a patient being treated with a lipase inhibitor an amount of a bile salt sequestrant effective to reduce the side effects associated with the lipase inhibitor treatment.

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